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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,701	09/30/1999	GEORGE H. LOWELL	406462000200	8314

500 7590 05/23/2006

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EXAMINER

PARKIN, JEFFREY S

ART UNIT PAPER NUMBER

1648

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/214,701

Applicant(s)

LOWELL, G. H., ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20, 21, 23, 24, 26-29, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20, 21, 23, 24, 26-29, 33 and 34 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to. 20, 21, 23, 24, 26-29
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>02/28/2006</u> | 6) <input type="checkbox"/> Other: _____ |

Serial No.: 09/214,701
Applicants: Lowell, G., et al.

Docket No.: 406462000200
Filing Date: 09/30/99

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 28 February, 2006. Claims 20, 21, 23, 24, 26-29, 33, and 34 are pending in the instant application.

Information Disclosure Statement

The information disclosure statement filed 28 February, 2006, has been placed in the application file and the information referred to therein has been considered.

37 C.F.R. § 1.75(c)

Claims 20, 21, 23, 24, and 26-29 are objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claims in proper dependent form, or rewrite the claim(s) in independent form. The claims do **not refer back** in the alternative only, or **refer to a preceding claim**, or reference two sets of claims with different features, or reference another multiple dependent claim. Refer to M.P.E.P. § 608.01(n).

35 U.S.C. § 112, Second Paragraph

The previous rejection of claims 19-24, 26-29, and 31 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is hereby withdrawn in response to applicants' amendment.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The previous rejection of claims 19 and 30-32 under 35 U.S.C. § 102(e) as being anticipated by Lowell (1998) is moot in view of applicants' response.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were

made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 20, 21, 23, 24, 26-29, 33, and 34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lowell (1998). Lowell (1998) describes the intranasal administration of a bacterial antigen comprising an endogenous hydrophobic sequence to a subject. This teaching also discloses the preparation of proteosomal compositions comprising both high-molecular weight proteins with an endogenous hydrophobic sequence, as well as, polypeptides covalently conjugated to an exogenous hydrophobic material comprising between 3 and 5 non-polar amino acids. It was reported (see col. 19, lines 10-12) that in "mice anti-SEB respiratory IgA and serum IgG were induced when the complexed compositions in saline were administered intranasally." The authors further added (bridging paragraph, cols. 19 and 20) that "Mice immunized intranasally with proteosome-toxoid vaccines were significantly protected ($p < 0.0117$) against systemic challenge with >4 LD₁₀₀ of SEB". The inventor also describes the preparation of gp160 vaccine compositions (see cols. 17 and 18, "gp160 Vaccine Against AIDS"). This teaching does not disclose the generation of mucosal neutralizing antibody responses to a modified gp160. However, this teaching clearly illustrates that vaccine compositions carrying high molecular weight proteins with endogenous hydrophobic sequences, when combined with a proteosome formulation and administered intranasally, are capable of inducing strong neutralizing mucosal antibody responses. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at

the time the invention was made to immunize a host with the gp160/proteosome composition taught by Lowell (1998) to induce a strong neutralizing mucosal antibody response, since this teaching clearly illustrates that proteosomes act as strong mucosal adjuvants. Moreover, Lowell (1998) also clearly teaches that proteosomes are capable of inducing neutralizing mucosal immune responses against high-molecular weight immunogens. Lowell also teaches that the combination of polypeptides, hydrophobic feet, and proteosomes induces strong immune responses. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to immunize a host with the polypeptide/hydrophobic foot/proteosome composition taught by Lowell (1998) to induce a strong neutralizing mucosal antibody response, since this teaching clearly illustrates that hydrophobic feet/proteosomes act as strong mucosal adjuvants.

Applicants traverse and submit that the teaching relied upon fails to render the claimed invention *prima facie* obvious. In response to Applicants' argument the test for analyzing references is what the disclosure taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 U.S.P.Q. 209 (C.C.P.A. 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 U.S.P.Q. 545 (C.C.P.A. 1969). In this case, all the claimed limitations are present in the prior art and both the motivation and a reasonable expectation of success were present in the prior art. Applicants' representative is invited to contact the examiner to discuss suggested revisions to the claim language.

Finality of Office Action

Applicants' amendment necessitated any and all new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P.

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Correspondence

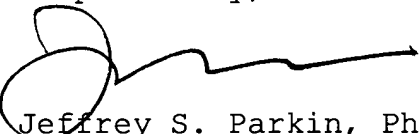
Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Serial No.: 09/214,701
Applicants: Lowell, G., et al.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

15 May, 2006